

Application No. 10/528,417
Paper Dated August 17, 2009
In Reply to USPTO Correspondence of March 16, 2009
Attorney Docket No. 0470-050863

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/528,417 Confirmation No. : 2537
Applicants : Martinus Antonius Hermanus Maria Wiegerinck, et al.
Filed : July 26, 2006
Title : SAMPLER
Group Art Unit : 3736
Examiner : Brian Scott Szmal
Customer No. : 28289

DECLARATION OF INVENTOR

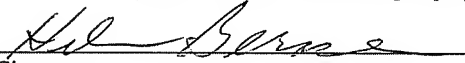
Sir:

Applicants submit this declaration by Martinus Antonius Wiegerinck along with an Amendment in response to the Office Action of March 16, 2009 and a Petition for a Two-Month Extension of Time.

I hereby certify that this correspondence is being electronically submitted to the United States Patent and Trademark Office on August 17, 2009.

Helen Gerace

(Name of Person Submitting Paper)

 08/17/2009
Signature Date

US patent application 10/528,417

declaration of inventor

I, Martinus Antonius Wiegerinck, hereby declare that the following is true. The interpretation of the prior art documents as discussed below is to my best knowledge what a person skilled in the art would learn from these publication.

The sampler which is subject of the present US application 10/528,417 has been invented by me.

For medical purposes, samples can be collected from body cavities of persons, e.g. cervical samples to test for cervical cancer. A long felt need exists to enable to collect samples in a non-medical surrounding, e.g. in a person's home environment. This would be more comforting for the person, and would take less time of medical staff to collect samples.

Before my invention, there have been no satisfying solutions known that address all necessary circumstances in a suitable manner.

The sampler according to the present invention has a number of structural features, which in combination have proven to be very effective for the intended purpose of the sampler, i.e. to collect samples containing cells from a body cavity.

The thickness of the tube (> 1 cm) provides an easy and painless guidance in a body cavity (e.g. to the top of the vagina, where the cervix is located) and good closure of the body cavity (such as the vagina), in order to allow expelling flushing fluid in the body cavity and to allow retrieval of a sample (flushing fluid plus cells) from the body cavity. This can be done while imparting as least as possible discomfort for the user when using the sampler: there is no or negligible spillage of flushing liquid, but also no discomfort from the part of the sampler in the body cavity because of the tubular and rounded form.

The feature that sampling openings are provided only at the curved end of the tube has the effect that a good flushing action is provided including separation of cells to be retrieved in the sample. This is especially the case when the body cavity is the vaginal cavity containing the cervix, and the sampler is used to collect cells from the cervical-vaginal region.

The feature that a central opening is present having a diameter of less than 5 mm has the effect that sufficient force of flushing fluid can be present, enhancing the effect to separate cells from the body cavity walls.

The feature that liquid containing means and pump means are present as an integral part of the sampler provide the effect that the sampler (in combination with the effects described above) is easy to use, e.g. at home. This makes the sampler particularly suitable for use in privacy (e.g. at home), while still ensuring that samples are being obtained with sufficient collected material for further research.

Therefore, the present sampler provides as an unexpected result that all the features as claimed contribute to the desired effect, i.e. to make a sampler which can be used in a non-medical environment, and which at the same time is very effective in taking samples of sufficient quality (i.e. with sufficient collected cells for further analysis).

Tests have been done using various embodiments of the sampler, and it has proven that the test persons are able to collect samples of sufficient quality with only minimal instruction on how to use the sampler.

I am aware of the documents as cited by the Examiner as relevant prior art documents.

To my understanding, Ayre (US 3,540,432) discloses a cytological sampling instrument having tubular means with curved distal end and storage means connected to tubular means, as well as vacuum means. The tubular means have a diameter of more than 1cm and openings only at curved distal end. Furthermore, the sampling instrument is provided with liquid containing means and pump means.

Mendoza (US6,071,231) discloses an instrument for artificial insemination for bovines and other animals. The instrument comprises a tubular shaped distal end, having a number of sampling openings only at the curved introduction end. A speculum is needed to introduce the instrument in the animal's body cavity. An inflatable balloon surrounding the distal end of the instrument is used to anchor the instrument in the correct position and to form a seal with the cervix of the animal's uterus, in order to deliver to the semen and diluent fluid to the uterus.

Suzuki (US4,781,699) discloses a mucus-removing device for sucking away mucus from an animal's uterocervical canal, as the mucus may interfere with the collection of embryos. As the intention of this device is to suck away mucus, to no surprise, a pump means or vacuum means is provided.

In my view, none of these documents disclose the combination of features as mentioned in the independent claim of my application. Moreover, even when combining the documents, the skilled person is not likely to arrive at the claimed invention: Ayre teaches a sampling instrument, but not with all features of my invention. Mendoza teaches about an insemination device, which needs to be properly positioned with respect to the uterus to be able to work properly. Nothing is taught about how to obtain a comfortable sampler for home use. Suzuki teaches about a mucus-removing device, and again nothing is taught or suggested to the skilled person about how to obtain the unexpected effects of the entire sampling device of my invention, as discussed above.

The skilled person in my view will only find the exact combination of features producing the effects as discussed above after reading my patent application, which is a clear indication that the present sampler is non-obvious.

Signed on August 13, 2009

Martinus Antonius Wiegerinck, Inventor

